



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	321874	Manuka Honey Cold & Flu
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Brauer Natural Medicine Pty Ltd	
<b>Postal Address</b>	PO Box 234, TANUNDA, SA, 5352 Australia	
<b>ARTG Start Date</b>	16/08/2019	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	Listed Medicines	

### Conditions

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Act, shall be only those included in the list of 'Colourings permitted in medicines for oral use'.

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Complementary Medicines Branch, Therapeutic Goods Administration, upon request.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.

### Products

#### 1 . Manuka Honey Cold & Flu

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	29/07/2022
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### Permitted Indications

- Antioxidant/Reduce free radicals formed in the body in children
- Helps reduce/decrease free radical damage to body cells in children
- Traditionally used in Homoeopathic medicine to relieve weariness/tiredness/fatigue/feeling of weakness in children
- Traditionally used in Homoeopathic medicine to relieve eye discomfort in children
- Maintain/support healthy eye function in children
- Maintain/support eye health in children
- Traditionally used in Homoeopathic medicine to relieve itchy eyes in children
- Traditionally used in Homoeopathic medicine to relieve eye redness in children
- Traditionally used in Homoeopathic medicine to relieve eye soreness
- Maintain/support healthy eyesight/vision in children
- Traditionally used in Homoeopathic medicine to decrease/relieve watery eyes/excessive lacrimation
- Maintain/support healthy growth and development
- Maintain/support body mucous membrane health in children
- Maintain/support general health and wellbeing in children
- Traditionally used in Western herbal medicine to maintain/support general health and wellbeing in children
- Traditionally used in Homoeopathic medicine to maintain/support general health and wellbeing in children
- Maintain/support general health and wellbeing when sun exposure is inadequate
- Maintain/support hair health in children
- Aids/assists teeth development in children
- Maintain/support healthy teeth in children
- Maintain/support teeth mineralisation in children
- Maintain/support teeth strength in children
- Maintain/support nail health/strength/thickness in children
- Maintain/support bone health in children
- Aids/assists healthy bone development/growth/building in children
- Maintain/support bone strength in children
- Help maintain/support bone mineralisation in children

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Maintain/support immune system health in children  
Traditionally used in Western herbal medicine to maintain/support immune system health in children  
Maintain/support healthy immune system function in children  
Traditionally used in Western herbal medicine to maintain/support healthy immune system function in children  
Maintain/support muscle function in children  
Maintain/support healthy neuromuscular system/function in children  
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve muscle pain/ache/soreness in children  
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve muscle tiredness in children  
Aid/assist/helps protein synthesis in the body in children  
Maintain/support absorption of dietary (state vitamin/mineral/nutrient) in children  
Maintain/support (state vitamin/mineral/nutrient) levels in the body in children  
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in children  
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient) in children  
Maintain/support cognitive function/mental function in healthy children  
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve mild dizziness/vertigo in children  
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve headache symptoms in children  
Maintain/support nerve conduction in children  
Maintain/support nervous system function in children  
Traditionally used in Homoeopathic medicine to decrease/reduce excess chest phlegm in children  
Traditionally used in Western herbal medicine to decrease/reduce/relieve common cold duration in children  
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of common colds and flu in children  
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of common colds and flu in children  
Linked indication - Enhance/improve/promote/increase cough productivity  
Linked indication - Decrease/reduce/relieve cough  
Linked indication - Decrease/reduce/relieve chills associated with common cold  
Linked indication - Decrease/reduce/relieve sneezing  
Linked indication - Decrease/reduce excess mucous  
Linked indication - Decongestant/relieve nasal congestion  
Linked indication - Relieve runny/dripping nose  
Linked indication - Decrease/reduce/relieve throat irritation  
Linked indication - Decrease/reduce/relieve throat mucous membrane irritation/inflammation  
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of head cold in children  
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of head cold in children  
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve mild upper respiratory tract congestion in children  
Traditionally used in Western herbal medicine to decrease/reduce/relieve the severity of symptoms of mild upper respiratory tract infections in children  
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve the severity of symptoms of mild upper respiratory tract infections in children  
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of sinusitis in children  
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve the severity of common cold symptoms in children  
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of common cold in children  
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common cold in children  
Linked indication - Decrease/reduce/relieve cough  
Linked indication - Expectorant/clear respiratory tract mucous  
Linked indication - Decongestant/relieve nasal congestion  
Linked indication - Sudorific/diaphoretic/enhance/promote sweating/perspiration  
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve mild bronchial cough in children  
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of laryngitis in children  
Traditionally used in Homoeopathic medicine to relieve symptoms of sore throat/pharyngitis in children  
Maintain/support skin health in children  
Maintain/support skin integrity/structure in children  
Maintain/support skin regeneration in children  
Maintain/support wound healing in children

**Indication Requirements**

Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.

Label statement: If symptoms persist, talk to your health professional.

Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).

If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

Product presentation must not imply or refer to serious immunological diseases.



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Product presentation must not imply or refer to mental illnesses, disorders or conditions.

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.  
 Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.

Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.

Product presentation must not imply or refer to chronic fatigue syndrome.

Respiratory tract infections must be qualified by 'mild'.

Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

Product presentation must only refer to mild bronchitis.

Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

Product presentation must only refer to mild vertigo.

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect).

(If medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect].

Not suitable for infants under the age of twelve months (or words to that effect).

Contains homeopathic ingredients.

Contains hydroxybenzoates (or words to this effect) if the medicines contains more than one hydroxybenzoate source OR Contains (insert the approved name of hydroxybenzoate used)(or words to this effect) if product contains one hydroxybenzoate source.

**Additional Product information**

**Pack Size/Poison information**

<b>Pack Size</b>	<b>Poison Schedule</b>
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**Components**

**1 . Formulation 1**

**Dosage Form** Oral Liquid

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>Allium cepa bulb (Homeopathic)</b>	<b>5 microlitre/mL</b>
<b>Anemone pulsatilla whole plant (Homeopathic)</b>	<b>5 microlitre/mL</b>
<b>betacarotene</b>	<b>.15 mg/mL</b>
<b>colecalfiferol</b>	<b>.0002 mg/mL</b>
<b>Echinacea purpurea herb top flowering Extract dry concentrate</b>	<b>6.675 mg/mL</b>
Equivalent: Echinacea purpurea (Dry)	26.7 mg/mL
<b>Euphrasia officinalis whole plant (Homeopathic)</b>	<b>5 microlitre/mL</b>
<b>Gelsemium sempervirens root and rhizome (Homeopathic)</b>	<b>5 microlitre/mL</b>
<b>Hedera helix leaf Extract dry concentrate</b>	<b>5 mg/mL</b>
Equivalent: Hedera helix (Dry)	20 mg/mL
<b>Honey</b>	<b>325 mg/mL</b>
<b>Honey</b>	<b>65 mg/mL</b>
<b>Mentha X piperita herb Extract dry concentrate</b>	<b>13.33 mg/mL</b>
Equivalent: Mentha X piperita (Dry)	66.65 mg/mL
<b>Sambucus nigra flower Extract dry concentrate</b>	<b>41.66 mg/mL</b>
Equivalent: Sambucus nigra (Dry)	250 mg/mL
<b>sodium chloride (Homeopathic)</b>	<b>5 microlitre/mL</b>
<b>zinc glycinate</b>	<b>.443 mg/mL</b>

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Equivalent: zinc

.125 mg/mL

**Other Ingredients (Excipients)**

dl-alpha-tocopherol  
ethanol  
Flavour  
glycerol  
maize starch  
maltodextrin  
methyl hydroxybenzoate  
modified food starch  
propyl hydroxybenzoate  
purified water  
silicon dioxide  
vegetable oil  
xanthan gum

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